

Integrated Risk Information System (IRIS) Program

At the National Center of Environmental Assessment (NCEA)

SUMMARY

What is an IRIS assessment?

- Created in 1985, IRIS assessments identify the potential for a chemical to cause cancer or adverse non-cancer health effects in people, and, when appropriate, include quantitative estimates of toxicity based on routes of exposure. **IRIS is the only federal program to provide toxicity values for both cancer and non-cancer effects.**
- IRIS assessments are not risk assessments or regulatory decisions. They are the top tier source of toxicity information used by EPA and other health agencies to inform national standards, clean-up levels at local sites, and set advisory levels. IRIS assessments inform decisions under the Clean Air Act, Clean Water Act, Safe Drinking Water Act, CERCLA/Superfund, and TSCA.
- The assessments are complex, multidisciplinary evaluations of scientific information, which are developed through a transparent and systematic process with robust, independent peer review.
- The IRIS Program utilizes a multi-step process which provides multiple opportunities for public, stakeholder, and interagency engagement. Assessments are developed with a focus on scoping and problem formulation to define user needs and frame the scientific questions prior to draft development, and incorporate scientific and public input at the outset.

CURRENT STATUS AND ISSUES

IRIS in 2017

- New leadership at both NCEA and the IRIS Program.
 - The new NCEA Director: With significant experience in the chemical industry, and former Director of ORD's Chemical Safety for Sustainability National Research Program, the new NCEA Director brings knowledge of TSCA, innovative applications of computational toxicology, and exposure science.
 - The IRIS Program Director: As a recognized leader in systematic review, automation, and chemical evaluations, the new IRIS Program Director brings experience in early partner and stakeholder engagement and input, and demonstrated ability to increase capacity and transparency in assessments.
- NCEA assessments are being consolidated into a portfolio of *Chemical Evaluation* products that optimize the application of best available science and technology. These products are being shaped for use by a diversity of clients, including TSCA, Superfund, States, and other Federal Agencies.
- In the Chemical Evaluation area, reorienting current IRIS Program activities and workflow to deliver near-term high priority standalone products to support TSCA, drinking water quality assessments, and Brownfields.

IRIS Program Reviews

- In recent years the IRIS Program has been criticized for the length of time to complete assessments, and transparency in the IRIS process. ORD and NCEA have made major changes to address the concerns with the IRIS program.
- *The GAO High Risk List* – IRIS and TSCA were added to the list in 2009 under the topic “Transforming EPA’s Processes for Assessing and Controlling Toxic Chemicals.” ORD has addressed a number of recommendations and is committed to resolving remaining issues to remove the IRIS Program from the High Risk List. In 2017, GAO acknowledged that IRIS made significant improvements, progressing from “not met” to “partially met” on two criteria—capacity and demonstrated progress, and from “partially met” to “met” in monitoring.
- *The NAS* – Reports in 2011 and 2014 provide recommendations for improvements to the IRIS Program. The 2014 NAS report commended Agency efforts to address recommendations. The Agency continues to implement actions to improve the fundamental science, increase capacity and increase transparency.
- ORD is addressing GAO and NAS recommendations:
 - Important steps have already been taken to improve the fundamental science, augment capacity, and increase transparency in response to GAO and NAS recommendations, all with opportunities for public and stakeholder involvement.
 - In 2017, additional improvements (e.g., use of specialized software) will further increase capacity and improve data-content management. These changes will improve data sharing with stakeholders, other Federal and State agencies, and support other important EPA initiatives, such as implementing amended TSCA.
 - Along with these efforts, EPA has requested that the National Academies convene a public meeting and independently review the progress of the IRIS Program in implementing the 2014 NAS recommendations. The NAS will convene a committee in FY2018, and issue a consensus report within six months.